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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/613,739	07/03/2003	Arthur M. Krieg	C01037.70043.US	4713
7590 02/07/2006			EXAMINER	
Maria A. Trevisan Wolf, Greenfield & Sacks, P.C. 600 Atlantic Avenue Boston, MA 02210			BROWN, TIMOTHY M	
			ART UNIT	PAPER NUMBER
			1648	

DATE MAILED: 02/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/613,739	Applicant(s) KRIEG, ARTHUR M.	
	Examiner Timothy M. Brown	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) See Continuation Sheet are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Continuation of Disposition of Claims: Claims pending in the application are 1-21,23,28-33,44,46-58,64-66,71-74,77-81,84,85,89,90,95,96,98 and 99.

Continuation of Disposition of Claims: Claims subject to restriction and/or election requirement are 1-21,23,28-33,44,46-58,64-66,71-74,77-81,84,85,89,90,95,96,98 and 99.

DETAILED ACTION

This Non-Final Office Action is responsive to the communication received December 19, 2005. Claims 1-21, 23, 28-33, 44, 46-58, 64-66, 71-74, 77-81, 84, 85, 89, 90, 95, 96, 98 and 99 are pending. Claims 22, 24-27, 34-43, 45, 59-63, 67-70, 75, 76, 82, 83, 86-88, 91-94 and 97 have been canceled.

This restriction requirement supplements the restriction requirement mailed November 15, 2005. The Examiner regrets any inconvenience caused by the failure to raise the new grounds for restriction appearing below.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-21, 23, 28-33 and 44, drawn to a composition comprising an immunostimulatory sequence and a *microbial antigen*, classified in class 536, subclass 23.1.
- II. Claims 1-21, 23, 28-33 and 44, drawn to a composition comprising an immunostimulatory sequence and a *cancer antigen*, classified in class 536, subclass 23.1.
- III. Claims 1-21, 23, 28-33 and 44, drawn to a composition comprising an immunostimulatory sequence and an *allergen*, classified in class 536, subclass 23.1.
- IV. Claim 99, drawn to a method for identifying an immunostimulatory nucleic acid, classified in class 435, subclass 7.21.

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- V. Claims 46-58, 64-66, 71-74, 77-81, 84, 85, 89, 90, 95, 96 and 98, drawn to a method of stimulating an immune response against a *microbial antigen*, classified in class 536, subclass 23.1.
- VI. Claims 46-58, 64-66, 71-74, 77-81, 84, 85, 89, 90, 95, 96 and 98, drawn to a method of stimulating an immune response against a *cancer antigen*, classified in class 536, subclass 23.1.
- VII. Claims 46-58, 64-66, 71-74, 77-81, 84, 85, 89, 90, 95, 96 and 98, drawn to a method of stimulating an immune response against an *allergan*, classified in class 536, subclass 23.1.
- VIII. Claims 46-58, 64-66, 71-74, 77-81, 84, 85, 89, 90, 95, 96 and 98, drawn to a method of stimulating an immune response against a *self antigen*, classified in class 536, subclass 23.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-III and Inventions V-VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together because the specification does not teach a process wherein the claimed antigens are administered simultaneously. For example, the specification does not teach administering a cancer antigen in combination with an allergan. Inventions I-IV also have different functions in that Inventions I-IV are drawn to processes for treating different diseases. For at least these reasons, Inventions I-IV are unrelated.

Inventions I-III and V-VIII are unrelated to Invention IV. This results because each of Inventions I-III and V-VIII has a different function than Invention IV. Inventions I-III and V-VIII are respectively drawn to compositions and methods for treating disease. Invention IV, in contrast, is a screening assay for identifying potential immunostimulatory sequences. Inventions I-III and V-VIII are therefore unrelated to Invention IV due to their different functions.

Inventions I-III are related to Inventions V-VIII as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In this case, Inventions I-III comprise a polynucleotide (i.e. immunostimulatory sequence). Because such a polynucleotide can be used to transform a cell line for the recombinant production of protein, or as a probe for identifying an oligonucleotide of interest, Inventions I-III can be used in a materially different process. Inventions I-III may therefore be restricted from Inventions V-VIII as product and process of use.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Claim 1 link(s) Inventions I-III, while claim 46 links Inventions V-VIII. The restriction requirement is subject to the nonallowance of linking claims 1 and 46. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are

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advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

An election of Invention I or V requires a further election of one of the following microbial antigen species is required:

- i. Bacterial
- ii. Fungal
- iii. Viral
- iv. Parasitic

Should Applicants elect to prosecute a viral antigen, a further election of one of the following species of virus is required:

- v. HIV
- vi. HTLV
- vii. HSV
- viii. HPV
- ix. HAV
- x. HBV
- xi. HCV
- xii. EBV

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- xiii. Cytomegalovirus
- xiv. Molluscum contagiosum virus
- xv. Haemophilus

Should Applicants elect to prosecute a bacterial antigen, a further election of one of the following bacterial species is required:

- xvi. Campylobacter
- xvii. Clostridium
- xviii. E. coli
- xix. Staphylococcus

Species i-xix are patentably distinct because they are unrelated. As noted above, inventions are unrelated if they are not disclosed as capable of use together, and have different functions. Here, the specification does not disclose using the antigens of Species i-xix simultaneously. Species i-xix also have different functions in that they are drawn to treating different diseases. Accordingly Species i-xix are unrelated.

An election of any of Inventions I-III requires a further election of one of the following species of composition:

- xx. An antigen
- xxi. An adjuvant
- xxii. A Cytokine

An election of Inventions I-III or V-VIII requires a further election of one of the following species of administration formula:

- xxiii. Mucosal

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xxiv. Parenteral

xxv. Local

Species xxiii-xxv are patentably distinct due to different modes of operation. Inducing an immune response using a particular administration route implicates different tissues, different cell types, different circulatory patterns and different immunological responses (e.g. systemic vs. mucosal). Moreover, influencing an immune response in a particular tissue often requires different types of immunogenic carriers.

An election of Invention II requires a further election of one of the following species of anticancer agent:

xxvi. Chemotherapeutic agent

xxvii. A cancer vaccine

xxviii. An Immunotherapeutic agent

Species xx-xxii are unrelated because they are drawn to treating different diseases and therefore have different functions.

An election of Invention II requires a further election of one of the cancer species listed in claim 95. These cancer species are patentably distinct because they are unrelated due to different their different functions. That is, the species limit the invention to treating different forms of disease.

An election of Invention III requires a further election of one of the species of allergy/asthma medicament listed in claim 15. These species are unrelated because they have different modes of operation. The chemical compositions give the species different biological

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activities and mechanisms of operation. The species are therefore unrelated due to their different modes of operation.

An election of Invention V requires the election of one of the following antimicrobial agents:

- xxix. Anti-bacterial agent
- xxx. Anti-viral agent
- xxxi. Anti-fungal agent
- xxxii. Anti-parasite agent

Species xxx-xxxiii are patentably distinct due to different functions; these species are drawn to agents that are used for treating different pathogens.

An election of Invention V requires a further election of one of the antigen species listed in claim 57. These species are distinct from one another because they give the claimed method a different mode of operation. That is, each of the antigens listed in claim 57 induces a specific immune response and therefore establishes a distinct form of immunological memory.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after

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the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Timothy M. Brown whose telephone number is (571) 272-0773. The examiner can normally be reached on Monday - Friday, 8am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Timothy M. Brown
Examiner
Art Unit 1648


2/6/06

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2/2/06